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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,650

04/21/2004

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EXAMINER

MOORE, SUSANNA

ART UNIT

PAPER NUMBER

1624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/828,650

Applicant(s)

PAHL ET AL.

Examiner

Susanna Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/5/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Remarks, filed 1/5/2007, with respect to the Non-Final Office Action mailed 10/11/2006 have been fully considered. The following objections and rejections are pending rejections from the previous office action or are necessitated by Applicants amendments. Claims 1-17 are pending in the Application.

Claim Objections

Claim 1 is objected to because of the following informalities: remove one of the “-“ from the named species in claim 1. Appropriate correction is required.

Claims 14 and 17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer back in the alternative. See MPEP § 608.01(n). Accordingly, the claims 14 and 17 have not been further treated on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill

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in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castelhanol et. al. (US 6,878,716), optionally in view of Engel et. al. (Inter. J. Pharm., 2000).

The instant Application teaches 4-(4-trans-hydroxy-cyclohexyl)amino-2-phenyl-7H-pyrrolo[2,3d]pyrimidine hydrogen mesylate.

Castelhanol et. al. teaches 4-(4-trans-hydroxy-cyclohexyl)amino-2-phenyl-7H-pyrrolo[2,3d]pyrimidine, see column 66, lines 32-33. The references also teaches the mesylate salt as pharmaceutically acceptable salts, see column 21, lines 1-2 and 13.

When the exact compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, obviousness can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is obvious. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of

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the compounds included in the generic formula before any of the compounds can be “at once envisaged.” It would be obvious of one of ordinary skill in the art to make the mesylate salt of the above-mentioned compound because mesylate is one of the specific salts taught in the reference. See column 21, lines 1-2 and 13

The reference also teaches the method of treatments and compositions thereof, see column 17, line 57 and column 20, lines 35-36 and thus, the references renders the instant claims obvious.

In addition, one would be motivated to specifically use the mesylate salt because mesylate salts are known to be more soluble than many other known salts. See the optional secondary reference, Engel et. al. (Inter. J. Pharm., 2000, 239-247).

Applicants first of all state the three basic criteria to establish a prima facie case of obviousness: 1) there must be some teaching, suggestion or motivation to modify the references’ teachings; 2) there must be a reasonable expectation of success; and 3) the references, when combined, must teach or suggest all the claim language. All three of these points will be discussed below as a whole.

Applicants begin by arguing the burden of establishing a prima facie case of obviousness lies with the USPTO. This is correct and the Examiner as satisfied this burden by the 103 art rejection given above. The examiner has focused on the invention as whole and applied the art to the appropriate claims. The primary reference did not suggest but taught 4-(4-trans-hydroxy-cyclohexyl)amino-2-phenyl-7H-pyrrolo[2,3d]pyrimidine and also taught a mesylate salt, as indicated above, which meets the limitations of claim 1 in the instant Application. No

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modifications of the reference were necessary, just following the teachings of the reference. The optional secondary reference, Engel et. al., provides the specific motivation to use a mesylate salt versus other salts to increase solubility. And as such, one of ordinary skill in the art would have been motivated to choose the mesylate salt over other salts to produce a more soluble version of the base compounds mentioned above.

Applicants cite *In re Baird* stating, “[a] disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds.” *Id.* at 383. Applicant has stated at the bottom of page 9, “this would encompass 4,966 salt/compound” acknowledging this is a low number and more could be mentioned from the “Detailed Description” portion of the reference. Even so, the instant case refers to thousands of compounds as opposed to the millions of compounds in Baird. Note *Merck & Co vs. Biocraft*, 10 USPQ 2nd 1843, 1846 in which a reference disclosing “more than 1200 combinations”, with no indication that any one of them was preferred over the others, was found to render each choice obvious. Note also *In re Corkill*, 226 USPQ 1005, 1008 and *In re Susi*, 169 USPQ 423, 425.

Concerning the unexpected results argument provided by Applicant, it is true that some 103 art rejections can be overcome by submitting a declaration with a side-by-side comparison of the test results of the compounds from the art references and the instant Application indicating the unexpected results. In this case, the prior art compound and the claimed species are the same. Applicants point to the Specification where there is a table of the solubility of the free base compound versus the polymorph alpha and beta mesylate salts. Applicants have not explained why these results are so unexpected, especially as one of ordinary skill in the art knows that salts

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are generally more soluble than the parent compound. That is one main reason why they are prepared. And the optional secondary reference, Engel, teaches this explicitly.

One final point, Applicant asserts the “unpredictability associated with salt/compound combinations was recognized by the Federal Circuit as an indication of non-obviousness,” citing *Sanofi-Synthelabo v. Apotex, Inc.* The difference between the Sanofi case and the instant is that in the Sanofi case, the bisulfate salt was a suitable salt for preparing the enantiomer salt, which process of preparing was not disclosed. In the instant case, the mesylate salt is disclosed for this purpose and by simply following the teachings of the reference one of ordinary skill in the art would naturally make the mesylate salt. Furthermore, a declaration was provided in the Sanofi case, which is not the same as the instant case. Moreover, just because salt formation was unpredictable in enantiomeric separations does not mean it is unpredictable here.

Conclusion

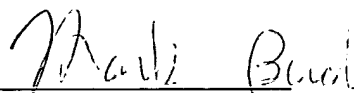
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Moore whose telephone number is (571) 272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SM



Mark L. Berch
Primary examiner
Art Unit 1624
Technology Center 1600